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10/664,711	09/17/2003	Budimir Drakulic	RECOM-64412	4390

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EXAMINER

LEE, YUN HAENG NMN

ART UNIT	PAPER NUMBER
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3766

MAIL DATE	DELIVERY MODE
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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/664,711

Applicant(s)

DRAKULIC, BUDIMIR

Examiner

Yun H. Lee

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 and 78-109 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-54 and 78-109 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/5/07 has been entered.

Claim Objections

2. The claims are objected to because of numerous informalities, the following being a few examples: In claim 1 lines 6-7, the limitation "the hearts of the patient" does not make sense since one patient has only one heart. In claim 1 lines 7-8, the limitation "the predetermined positions" lacks proper antecedent basis. In claim 1 lines 11-12, the limitation "the individual positions" lacks proper antecedent basis. In claim 96 line 2, the limitations "the amplifiers" lacks proper antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 42 and 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Examiner does not find in the specification a disclosure of electrodes disposed in a third plurality of positions in the upper right portion of the vest and a fourth plurality of positions in the lower left portion of the vest, the third and fourth pluralities of positions being disposed in the rear of the vest.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 1-6 and 95 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.

Examiner finds Applicant's claim of an amplifier that produces signals without interference from noise and/or independent of noise that may result from ambulation of the patient to be incredible.

Claims 1-6 and 95 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-4, 7-11, 16, 19-24, 29, 30, 32-41, 44-54 and 78-109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greene (US Pat. No. 3,525,330).

Regarding claim 1, Greene discloses in a combination for providing signals at different positions in a patient,

a vest (10) constructed to be worn by the patient when the patient has a small, medium or large size,

a plurality of electrodes (col. 1 lines 22-23), and

the electrodes providing signals indicating characteristics of the heart of the patient having individual ones of the small, medium and large sizes, the positions of the electrodes for patients of each individual one of the small, medium and large sizes being different from the positions of the electrodes for the patients having the other ones of the small, medium and large sizes (col. 1 lines 56-58).

Examiner took Official Notice in a previous Office Action that it is extremely old and well known to use amplifiers when dealing with biological signals in order to reduce noise, buffer signals, and provide a gain or amplitude increase. Lacking adequate traversal, this feature has been taken to be admitted prior art. Some examples of this well-known feature can be found in Lasch et al. (US Pat. No. 3,554,188), Sipple (US Pat. No.

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3,565,060) and Day (US Pat. No. 3,611,174) just to list a few. Thus, it would have been obvious to one of ordinary skill in the art to use amplifiers responsive to the signals on the electrodes at the individual positions in the vest of Greene for the patients having the individual one of the small, medium and large sizes for providing signals indicating the characteristics of the patient's heart at the different positions for the patient and with characteristics corresponding to the characteristics of the signals at the electrodes. Since the amplifiers would receive the signals from the electrodes, the signals that are provided by the amplifiers will necessarily have characteristics corresponding to the characteristics of the signals at the electrodes.

Regarding claim 2, Applicant admits in the present specification (page 10 lines 4-5) that the V_1 - V_6 positions are well known in the prior art. Thus, it would have been obvious to one of ordinary skill in the art to position the electrodes of Greene at the positions V_1 - V_6 .

Regarding claim 3, Greene further discloses that the electrodes are disposed on the vest in rows and columns (col. 2 lines 36-43). Each of the electrodes in the vest will inherently be disposed in the vest in an individual one of the columns relative to the disposition of the other electrodes in the vest when the patient has an individual one of the small, medium and large sizes if the electrodes are positioned to measure V_1 - V_6 positions since, by definition, these positions do not overlap vertically.

Unity gain amplifiers such as those claimed in claim 3 are well known, as evidenced by Applicant's admission in the specification (col. 16 lines 19-20) that such

amplifiers are commercially available. Examiner takes Official Notice that it is well known to employ unity gain amplifiers to ensure that doing a measurement of a voltage does not disturb the circuit producing the voltage to be measured. Certainly, Applicant is not the first to discover the utility of unity gain amplifiers. Thus, it would have been obvious to one of ordinary skill in the art to employ unity gain amplifiers in the vest of Greene.

Regarding claim 4, Greene further discloses that the positions in the vest are disposed in rows and columns (19). Each of the amplifiers, as discussed above, will inherently provide indications of the heart in an individual one of the rows at an individual one of the columns when the patient has the individual one of the small, medium and large sizes if the electrodes which provide the signals indicating the characteristics of the patient's heart at the different positions for the patient when the patient has a small, medium or large size are positioned to measure V_1 - V_6 positions.

Regarding claims 7-11, and 19, the limitations are met by the above discussion.

Regarding claims 16, 20-24, 29, 30 and 49-54, Examiner took further Official Notice in a previous Office Action that it is old and well known to include a low-pass filter in an amplifier used for ECG signals to eliminate noise and other signal contaminants. One example of such an amplifier can be found in Taylor et al. (US Pat. No. 6,304,773).

Lacking adequate traversal, this feature is taken to be admitted prior art. Thus, it would

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have been obvious to one of ordinary skill in the art at the time of invention to include a low-pass filter in the amplifier discussed above to eliminate noise and other signal contaminants, substantially eliminating noise in the signals to a level below that affecting the characteristics of the signals, regardless of the size of the patient during ambulatory movements of the patient.

Regarding claims 32-39, the various claimed electrode configurations are simply in accordance with the V_1 - V_6 positions which is old and well known as discussed above. Thus, the limitations are met by the above discussion.

Regarding claims 40, 41, 44 and 45, the limitations are met by the above discussion.

Regarding claim 46, the terms "relatively common problems" and "relatively uncommon problems" are extremely broad in scope. Examiner takes the position that electrodes disposed in various positions are capable of providing signals indicative of "relatively common problems" as well as "relatively rare problems". Greene discloses various positions for the electrodes, including the front of the patient (such as in the V_1 - V_6 positions) and the back of the patient (col. 1 lines 35-37).

Regarding claims 47, 48 and 78-109, the limitations are met by the above discussion.

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9. Claims 5, 6, 12-15, 17, 18, 25-28 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greene (US Pat. No. 3,525,330) in view of the above discussion and further in view of Heilman et al. (US Pat. No. 5,078,134). Greene in view of the above discussion meets all the limitations of claims 5, 6, 12-15, 17, 18, 25-28 and 31 except for an inflatable member for inflating the vest/electrodes. Heilman et al. discloses an inflator (322) for inflating a vest/electrodes against the patient's body to reduce the impedance at the electrode/skin interface (col. 12 lines 20-21). Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to include an inflator in the vest/electrodes of Greene for inflating the vest/electrodes against the patient's body to reduce the impedance at the electrode/skin interface.

Response to Arguments

10. Applicant's arguments filed 6/5/2007 have been fully considered but they are not persuasive. Examiner would like to start out by clarifying two points: 1) Greene discloses two different vests identified by the labels 10 and 41. Note that Examiner cites 10 as the garment that reads on Applicant's claimed invention. 2) Greene discloses supplying the fitting garment 10 in a number of standard sizes (col. 1 lines 52-54). The largest available size will be capable of being worn by a patient regardless of whether the patient has a small, medium or large size. Once the patient is wearing the fitting garment, the electrodes can be fitted onto the V₁-V₆ positions in accordance with the patient's body. The arrangement of the electrodes will differ depending on whether

the patient has a small, medium or large size. These two points should serve to counter most of the Applicant's arguments.

In the latter half of page 30 of the arguments, Applicant cites Greene column 1, lines 55-57 to argue that Greene does not indicate or suggest that individual positions are disposed to receive the electrodes when the patient has a small, medium or large size. But the process of placing electrodes that is described in Greene column 1, lines 55-57 is the same process that is used by Applicant to place electrodes. Applicant also personalizes the placement of electrodes on the vest to a particular individual for whom the vest is being fitted, this particular individual being a patient having a small, medium or large size.

Applicant continues to state the fact that some claimed limitations are not disclosed by the references cited by Examiner. Examiner strongly suggests that, before making such statements, Applicant take a closer look at the rejections to verify whether Examiner stated that these limitations are disclosed by the references cited by Examiner or whether Examiner took Official Notice regarding these limitations.

Finally, Examiner would like to mention that the fact that a certain feature or improvement was not documented does not, by itself, prove that the feature or improvement was non-obvious.

Conclusion

11. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the

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grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yun H. Lee whose telephone number is (571) 272-2847. The examiner can normally be reached on M-Th 10-8.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kennedy J. Schaetzle/
Primary Examiner, Art Unit 3766
July 30, 2007

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